Applicant: Michael R. Dupelle et al. Attorney's Docket No.: 04644-101001

Serial No.: 09/938,063 Filed: August 23, 2001

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REMARKS

The examiner has rejected the independent claims (11, 16) under 35 USC 103 as being unpatentable over Gliner in view of Ferrari and Smiths Industries.

A new independent claim 26 replaces the existing independent claims. (This amendment of the claims, as is true of prior amendments, is not to be construed to be an acceptance of any of the examiner's positions. The option of pursuing claims of the original scope in a continuation is preserved.)

The examiner is urged to reconsider and withdraw the rejection in view of new claim 26.

The invention as defined in the new claim differs in a great many respects from the teaching of the examiner's references, even if we assume (contrary to reason and fact) that there is motivation to combine the references in the manner suggested by the examiner.

The invention contemplates an electrode pad assembly having two defibrillation electrodes separated by a non-electrode area positioned between the two electrodes. There is an adhesive area at each electrode, and a non-adhesive area separating the adhesive areas. There are at least two release liners, with at least one release liner covering each adhesive area.

The assembly is attached to the patient's chest by first aligning the assembly on the chest. Then, one hand is used to hold the assembly in the desired position, generally by applying pressure in the non-electrode area, while the other hand pulls a tab to remove a release sheet at one of the electrodes. Then, the process is repeated for the other electrode.

The invention enables precise positioning of the electrode assembly, because the assembly can be positioned before the adhesive is exposed, and then it can be held in the desired position using one hand to press down and the other to remove first one release liner and then another release liner.

The release liners are configured so that when a tab is grasped and pulled to remove them, the movement is away from the non-electrode area. This direction of movement of the release liner assists in maintaining the alignment of the assembly during removal of the release liner, as the force applied to remove the liner is resisted by the pressure applied generally to the non-electrode area, without the assembly rotating and becoming misaligned.

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Gliner teaches an electrode assembly with two defibrillation electrodes and a central nonelectrode area, but that is as close as the reference gets to the claimed invention.

Gliner expresses no preference for whether the adhesive areas at the electrodes are separated by a nonadhesive area. The patent suggests putting adhesive under the entirety of the assembly, as well as leaving out adhesive in the central area. No preference is taught for one configuration over another (col. 4, lines 32-36).

Gliner also suggests nothing that would lead the reader toward associating a different release liner with each electrode. Quite to the contrary, Gliner teaches using a single, large release placard from which the electrode assembly is removed before placement (Fig. 7; col. 3, lines 14-15).

Most fundamentally, Gliner teaches squarely away from the concept of aligning the electrode assembly <u>before</u> removing the release liner. Gliner teaches the very opposite. The entire release liner is removed, and the sticky assembly is then positioned on the chest. All of the alignment problems that the present invention solves are present in Gliner. The user gets just one chance to get alignment right with the Gliner construction.

The examiner would solve all of these shortcomings of Gliner by imagining that the prior art would combine Gliner with Smiths Industries, which teaches the use of release liners in wound dressings.

In the first place, the two fields of art are not analogous. One skilled in the art of designing defibrillator electrode assemblies would not look to wound dressings for guidance, and vice versa. Second, there is no motivation taught in either reference to make the combination. The principal reason that release liners are used in wound dressings is to solve the problem of the dressing, which is very thin, being applied with wrinkles. That motivation does not apply to defibrillator electrode pad assemblies, which are not subject to wrinkling because of their greater thickness.

But even if one skilled in the art did have before him both Gliner and Smiths Industries, that hypothetical person would still not be in possession of the invention.

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None of the differences between Gliner and the claimed invention as outlined above – a non-adhesive area between the adhesive areas of the electrode, using at least one different release liner for each electrode, and removing the release liners after the electrode assembly is positioned on the chest – would be altered if the release liner approach taught in Smiths Industries were applied to Gliner.

What one skilled in the art is most likely to do in making the combination is to replace the Gliner release liner with the Smiths Industries release liner. Thus, the single release placard of Gliner would be replaced with a pair of release liners as shown in Smiths Industries. The release liners would extend across the entire undersurface of the electrode pad assembly. The user would remove the placard by removing two release liners, and then, after the release liner is fully removed, the user would apply the assembly to the patient.

The clever configuration of the invention, in which the electrode assembly is first positioned on the chest prior to removal of the release liners, and then held in position with one hand generally by applying pressure to a non-electrode area, while the other hand is used to remove a release liner from an electrode, certainly would not result from combining the two references. Likewise, the invention's arrangement that the direction in which the release liners is pulled is generally away from the non-electrode area could not possibly result from the combination.

Accordingly, claim 26 is in condition for allowance.

The remaining claims are all properly dependent on one or more of the independent claims, and thus allowable therewith. Each of the dependent claims adds one or more further limitations that enhance patentability, but those limitations are not presently relied upon. For that reason, and not because applicants agree with the examiner, no rebuttal is offered to the examiner's reasons for rejecting the dependent claims.

Allowance of the application is requested.

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Respectfully submitted,

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